K041993

AUG 16 2004

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510(k) SUMMARY

Submitter's Name and Address	Boston Scientific Corporation 3574 Ruffin Road San Diego, CA 92123
Contact Person	Renuka Krishnan Principal Specialist, Regulatory Affairs (858)503-1815
Common or Usual Name	PTA catheter
Product Code	LIT
Classification	Class II
Proprietary Name	2 cm Peripheral Cutting Balloon™

Predicate Devices

Boston Scientific 1 cm Peripheral Cutting Balloon™, K040155
Boston Scientific Ultra-Thin Diamond Balloon Dilatation Catheter, K960501
Polarcath™ Peripheral Balloon Catheter system, K030742
CVSi Peripheral Balloon Catheter system, K022061

Device Description

The 2 cm Peripheral Cutting Balloon (2 cm PCB) is a product line extension to the 1 cm Peripheral Cutting Balloon, and uses longer balloons to support 2 cm blades. It is available in nominal balloon diameters of 5.0 mm to 8.0 mm (Table 1). The device features a non-compliant balloon with four Atherotomes (microsurgical blades) mounted longitudinally on its outer surface. The catheter body has two lumens. The outer lumen is the balloon inflation lumen. The inner lumen is used to pass the catheter over a guidewire. Radiopaque markers are placed on the guidewire tubing at the ends of the atherotomes to provide visual reference points for balloon positioning within the vessel. One end of the catheter is attached to a Y-connector, the other end is attached to the balloon. The Rated Burst Pressure (RBP) of the device is 10 atm. The device is compatible with 0.018" guide wire.

Table 1. Model Numbers, 2 cm PCB

Nom. Diameter (mm)	*Catheter Length*		
	50 cms	*90 cms*	*135 cms*
5.0	PCB502050	PCB502090	PCB5020135
6.0	PCB602050	PCB602090	PCB6020135
7.0	PCB702050	PCB702090	PCB7020135
8.0	PCB802050	PCB802090	PCB8020135

Intended Use

The 2 cm Peripheral Cutting Balloon catheters are recommended for Percutaneous Transluminal Angioplasty of obstructive lesions in synthetic arteriovenous dialysis fistulae.

Substantial Equivalence

The Peripheral Cutting Balloon catheters will incorporate a substantially equivalent design, fundamental technology and intended use as those featured in predicate devices.

Performance Testing

Bench testing and biocompatibility testing were performed to support a determination of substantial equivalence. The results of these tests provide reasonable assurance that the proposed device has been designed and tested to assure conformance to the requirements for its intended use.

Conclusion

The 2 cm Peripheral Cutting Balloon catheter has been shown to be Substantially Equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 16 2004

Boston Scientific Corporation
c/o Ms. Renuka Krishnan
Principal Specialist, Regulatory Affairs
3574 Ruffin Road
San Diego, CA 92123

Re: K041993
2 cm Peripheral Cutting Balloon™
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous Catheter
Regulatory Class: Class II (two)
Product Code: LIT
Dated: July 22, 2004
Received: July 23, 2004

Dear Mr. Krishnan:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050. This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4646. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97) you may obtain. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE

510(k) Number (if known): K041993

Device Name: 2 cm Peripheral Cutting Balloon™

Indications For Use:

The Peripheral Cutting Balloon™ catheters are indicated for Percutaneous Transluminal Angioplasty of obstructive lesions of synthetic arteriovenous dialysis fistulae.

Prescription Use: **Yes** AND/OR Over-The-Counter Use: **No**
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Donna R. Lechner

(Division Sign-Off)
Division of Cardiovascular Devices

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